U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

March 13, 2019

TO: Republican Members, Subcommittee on Health

FROM: Republican Committee Staff

RE: Hearing entitled, "Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition"

I. INTRODUCTION

The Subcommittee on Health will hold a legislative hearing on Wednesday, March 13, 2019, at 10 a.m. in 2123 of the Rayburn House Office Building. The hearing is entitled, "Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition."

II. REPUBLICAN WITNESSES

- Kurt Karst, Director, Hyman Phelps & McNamara, P.C.
- Jeffrey P. Kushan, Partner, Sidley Austin LLP
- Chester "Chip" Davis, Jr., President & CEO, Association for Accessible Medicines

DEMOCRSTIC WITNESSES

- Lou Kennedy CEO and Owner Nephron Pharmaceuticals
- Anthony Barrueta Senior Vice President, Government Relations Kaiser Permanente
- Michael Carrier Distinguished Professor Rutgers Law School
- Marc M. Boutin, JD Chief Executive Officer National Health Council

III. BACKGROUND

The Drug Price Competition and Patent Term Restoration Act of 1984, popularly known as "Hatch-Waxman" established the abbreviated approval pathway for generic drugs.[1] The Hatch-Waxman framework included policies to facilitate the earliest possible market entrance of generic drugs to compete with the reference, or brand-name, drugs to which they are equivalent. Hatch-Waxman incentivizes generic product developers to conduct necessary testing and to challenge patent protections of brand drugs by granting the first generic filer with 180 days of exclusivity. Thus, the first generic drug developer with a substantially complete application gains the opportunity to market their product without competition from other generics for six months. This provision has proven to be successful in spurring generic product developers to challenge patents, often resulting in the launch of generic competition to drugs long before all applicable patents have expired. The Biologics Price Competition and Innovation Act of 2009 (BPCIA) created an abbreviated approval pathway for biological products shown to be biosimilar to a reference biological product.

[1] Pub. L. No. 98-417

These laws are just two examples of actions Congress has taken to facilitate a competitive pharmaceutical marketplace, and over time Congress has examined and modified existing policies to ensure they are working as intended. For instance, under Hatch-Waxman, generic product developers had the ability to gain 180-day exclusivity but not actually launch their product, effectively blocking all subsequent competitors from coming to the market. Congress addressed this loophole in the Medicare Modernization Act of 2003 by establishing criteria that would lead to forfeiture of 180-day exclusivity if certain criteria are met.[2]

Congress's efforts have been implemented successfully, 2018 marked the highest number of combined generic drug approvals and tentative approvals in the history of the Food and Drug Administration's (FDA) generic drug program.

IV. LEGISLATION

A. H.R. 965, the "Creating and Restoring Equal Access to Equivalent Samples Act of 2019" or the "CREATES Act of 2019"; and H.R. 985, the "Fair Access for Safe and Timely Generics Act of 2019" or the "FAST Generics Act of 2019".

Under Hatch-Waxman and BPCIA, in lieu of clinical trials establishing safety and efficacy, product developers must show FDA that a product is equivalent to the reference product through comparative testing. To conduct such testing, product developers must obtain a sufficient quantity of the reference product. There is no formal process in place for obtaining samples of the reference product, but the approval of generic applications is evidence that these transfers are taking place. However, there have been concerns that restricted distribution systems established to improve safety of inherently dangerous products makes samples more difficult to access in limited circumstances. Two of the bills being considered today attempt to address that concern.

Under H.R. 965, the CREATES Act, an eligible product developer can file suit against a license holder of a FDA-approved drug or biological product alleging the license holder has declined to provide a sufficient quantity of the covered product on "commercially reasonable, market-based terms". If the developer prevails they receive samples of the product and may be awarded damages up to all revenue earned by the brand manufacturer on the relevant product for the period of time starting at the request for samples until settlement. Under H.R. 985, the FAST Generics Act, a prevailing developer can be awarded treble damages including costs and interest as set forth in the Clayton Act.

B. H.R. 1499, the "Protecting Consumer Access to Generic Drugs Act of 2019".

Under Hatch-Waxman, when submitting a generic drug application, the prospective generic can make one of four certifications related to the patents on the products. A paragraph (iv) certification states that a patent is invalid or would not be infringed by the generic product. Paragraph (iv) certifications often start patent litigation. In some instances, the litigation results in a settlement where the brand manufacturer pays some amount to the generic manufacturer and agrees that the generic manufacturer can enter the market at a date prior to the expiration of the challenged patent, but later than they would have if the patent were found invalid ("pay-for-

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[2] *See* 21 U.S.C. §(j)(5)(D)(I)-(VI).

delay"). H.R. 1499, the Preserve Access to Affordable Generics and Biosimilars Act, would amend the Federal Trade Commission Act to create a presumption that these agreements are anticompetitive.

In the 2013 case, *FTC v. Actavis*, the Supreme Court held that a branded drug manufacturer's reverse payment to a generic competitor to settle patent litigation can, depending on the facts of an individual case, violate the antitrust laws. Since that time there has been a steady decrease in these settlements. The FTC reported in November 2017 that only 5 of the 170 final settlements in FY15 include compensation to the generic and a restriction on generic entry.

C. H.R. 938, the "Bringing Low-cost Options and Competition while Keeping Incentives for New Generics Act of 2019" or the "BLOCKING Act of 2019".

The first generic to file a substantially complete application under a paragraph (iv) certification can be granted 180 day of exclusivity to sell their product without other generic competition. This 180-day period was established to incentivize generics to challenge the patent of the brand and thus have generics come to market quicker. Some "first filers" receive "tentative" approval of their application but delay receiving "final" approval and thus delay the start of the 180-day exclusivity clock and subsequent generic approvals.

H.R. 938, the BLOCKING Act, makes the tentative approval of a subsequent generic drug applicant that is blocked solely by a first applicant's 180-day exclusivity, where the first applicant has not yet received final approval, a trigger of the first applicant's 180-day exclusivity.

D. H.R. 1506, the "Fair and Immediate Release of Generic Drugs Act of 2019" or the "FAIR Generics Act of 2019".

H.R. 1506, the FAIR Generics Act, would disqualify from being a "first filer" any generic applicant that enters into a "pay-for-delay" agreement where subsequent filers meet certain criteria. This bill would essentially allow multiple generics to share in the 180-day exclusivity.

E. H.R. 1503, the "Orange Book Transparency Act of 2019"; and H.R. 1520, the "Purple Book Continuity Act of 2019".

The Orange Book is a useful tool for developers of generic drugs, providers, payors, and patients. It is a resource maintained by the FDA as required by Hatch-Waxman and provides basic information on brand drugs and whether or not there is generic competition, as well as any information about intellectual property protection that would impede the entry of generic competitors. FDA has the authority to make changes and improvement to the Orange Book and announced that it is going to launch a public process to determine which patents should and should not be listed. [3]

H.R. 1503, the Orange Book Transparency Act, Codifies the current requirement to list drug substance patents, drug product patents, and method-of-use patents; allows the listing of

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[3] *See* Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency's efforts to enhance the utility of the Orange Book to foster drug competition. *available at* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm630098.htm.

other patents at agency discretion; and prohibits the listing of drug-delivery device patents. It further requires manufacturers to notify FDA of any court decision finding a patent invalid, and requires that FDA remove those patents from the Orange Book.

The Purple Book is essentially the equivalent to the Orange Book, but for large molecule, complex biologics. It is not required by law and is published by the FDA at their discretion. Last year FDA announced plans to enhance and improve the utility of the Purple Book in the Agency's Biosimilars Action Plan.[4]

H.R. 1520, the Purple Book Continuity Act, codifies the requirement to list: name of biologic; date of licensing; studies necessary for biosimilar applications; updates every 30 days; patents disclosed during "patent dance"; and withdrawal or suspension of licensure. The bill also requires FDA to report recommendations of what patents should be listed in the Purple Book going forward.

V. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Danielle Steele of the Committee staff at (202) 225-3461.

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[4] Food & Drug Admin., BIOSIMILARS ACTION PLAN: Balancing Innovation and Competition, *available at* https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM613761.pdf.